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LIEBERMAN

DECISION

THE COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

2-1153

FILE: B-205826 DATE: March 16, 1982

MATTER OF: Paramex Labs, Inc.

DIGEST:

Determination by Food and Drug Administration (FDA) that supplier of drug is unacceptable because it does not possess an approved application "ANDA," which FDA finds is required for marketing the drug, is not subject to review by GAO.

Paramex Labs, Inc. (Paramex), protests the anticipated rejection of its bid by the Defense Logistics Agency (DLA) under solicitation No. DLA120-81-B-2404, for hydrocortisone USP, on the basis that Paramex is not a responsible bidder. Apparently, DLA has suspended further action on this procurement pending our decision.

Paramex submitted the low bid under the solicitation. DLA requested the Food and Drug Administration (FDA) to perform a preaward quality survey of Paramex. The FDA found that the product requires a new drug application (NDA) or an abbreviated new drug application (ANDA) as a prerequisite to marketing. The FDA found that Paramex has neither an approved NDA nor ANDA; therefore, the firm did not possess the requisite quality assurance necessary to be an acceptable supplier under the solicitation.

Paramex protested to our Office, alleging that DLA should disregard the FDA finding. Paramex asserts that FDA is incorrect that an ANDA or NDA is required for the hydrocortisone in question in the form in which it will be supplied. Paramex also asserts that DLA has made previous awards of contracts for the product to suppliers which did not hold an approved ANDA or NDA.

DLA correctly argues that our Office no longer reviews protests involving the rejection of a bid because of nonconformance with a requirement within the cognizance of the FDA. Carlisle Laboratories, Inc., B-186987, B-187059, B-187131, February 22, 1977, 77-1 CPD 124; Lemmon Pharmacal Company, B-189048, July 25, 1977, 77-2 CPD 47. As DLA points out,

the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 355 (1976), prohibits any person from introducing a new drug into interstate commerce without filing an application and obtaining approval from the FDA. The stated grounds of this protest relate to the determination of the new drug status of a drug, a matter which is within the jurisdiction of the FDA. Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645, 653 (1973). Accordingly, we will not consider this aspect of the protest.

The DLA report to our Office indicates that, to date, Paramex has not been determined to be nonresponsible and the bid has not been rejected. Since Paramex has certified in its bid that it is a small business, we expect that any nonresponsibility determination by DLA will be referred to the Small Business Administration for consideration under the certificate of competency procedures, as required under the Small Business Act, 15 U.S.C. § 637(b)(7) (Supp. I, 1977). International Business Investments, Inc.; Career Consultants, Inc., 60 Comp. Gen. 275 (1981), 81-1 CPD 125.

Harry R. Van Cleve
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Acting General Counsel